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| 09/445,439 | 02/23/2000 | BERNHARD A. SABEL | NPA 100 | 9939 |

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EXAMINER

HARTLEY, MICHAEL G.

ART UNIT PAPER NUMBER

1616

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/445,439

Applicant(s)

SABEL ET AL.

Examiner

Michael G. Hartley

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 101-122, 132, 133, 135 and 136 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 102, 105, 108, 112, 114, 117, 118, 120, 122, 133, 135 and 136 is/are rejected.
- 7) ☒ Claim(s) 110 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 101,103, 104,106,107,109,111,113,115,116,119,121 and 132.

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Response to Amendment

The amendment filed 6/08/2004 has been entered.

Election/Restrictions

Newly submitted (amended) claims 101, 103, 104, 106, 107, 109, 111, 113, 115, 116, 119, 121 and 132 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: 1) the claims have been amended from a method of preparing a drug delivery system having nanoparticles to a method of administering an effective substance to the CNS. The methods are distinct in that the originally filed claims namely claim 101 and its dependent claims, that were drawn to a method of preparing a nanoparticle formulation, which is classified in 264/4.1 and did not require the steps of administration to the CNS, which is classified in 424/489. The originally filed claims were a method for preparing comprising a polymerizing step and then providing a medium for the nanoparticles. Since the methods of making originally filed did not require administration of a method of administering to the CNS, these claims are distinct due to the different steps, functions, etc. set forth therein. For example, the methods of making the nanoparticles originally filed were useful in various other methods, such as, treating non-CNS tissues, in vitro assays (drug tests), etc.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 101, 103, 104, 106, 107, 109, 111, 113, 115, 116, 119, 121 and 132 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 102, 105, 108, 112, 114, 117, 118, 120, 122, 133, 135 and 136 are rejected under 35 U.S.C. 102(a) as being anticipated by Reszka (The Jour. of Pharmaco. and Exp. Therap., 1/1997, AW-PTO-1449), for the reasons set forth in the office action mailed 12/8/2003.

Applicant's arguments filed 6/8/2004 have been fully considered but they are not persuasive.

Applicant arguments concerning claims 101 (and the claims dependent thereon), that Reszka does not disclose administration to the CNS is not relevant, as these claims have been withdrawn by original presentation, as set forth above.

Applicant also asserts that Reszka does not disclose a method of preparing nanoparticles as claimed (in claim 102) because Reszka does not teach a step of loading the drug for the treatment of a CNS disorder.

This is not found persuasive because Reszka discloses a method of preparing nanoparticles having the same steps as claimed, which include loading the nanoparticles with an anticancer drug (mitoxantrone). This is clearly within the scope of the drug as claimed, as dependent claim 117 defines such a drug as "anticancer drugs" and "cytostatic agents for the treatment of cancer." Since Reszka discloses a drug that is directly within the scope as claimed, it must have the same properties and be within the scope of a drug for the treatment of a CNS disorder as claimed. Since Reszka discloses a method of making nanoparticles by loading the same drug as claimed, it is unclear how applicant can use this to differentiate over Reszka.

Applicant also asserts that the claimed nanoparticles specifically exclude coatings.

This is not found persuasive because first the claims are not drawn to nanoparticles, only to a method of preparing. More importantly, Reszka discloses method in which no coating step is performed. However, it is unclear how this lack of coating can be used to differentiate the presented claims, as there are no limitations in the claims that specifically exclude a coating method, because the method of claim 102 states "comprising" which is open-ended and does not exclude additional steps, e.g., a coating step. The "consisting essentially of" later in the claim would, at most, only require that one start with

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nanoparticles having mainly only the components listed thereafter in the method. The method, as claimed, would not exclude a coating step later on, as the claim states that the method recites "comprising" terminology as to the steps involved.

Claims 102, 105, 108, 112, 114, 117, 118, 122, 133, 135 and 136 are rejected under 35 U.S.C. 102(b) as being anticipated by Beck (Jour. of Microencapsulation, 1993, PTO-892), for the reasons set forth in the office action mailed 12/8/2003.

Applicant's arguments filed 6/8/2004 have been fully considered but they are not persuasive.

Applicant asserts that Beck does not disclose nanoparticles without a surfactant for delivery of a compound to the CNS.

As set forth above, the rejected claims are drawn to a method of preparing a nanoparticle formulation, not nanoparticles for delivery of a compound to the CNS. Beck discloses a method of preparing a nanoparticle formulation having the same steps as claimed. Also, the drug loaded in the nanoparticles in the method disclosed by Beck is within the scope of the drug loaded in the claimed methods. This is seen by dependent claim 117, which defines the drug as an anticancer agent. Clearly, the drug loaded in the methods of preparing the nanoparticle formulation of Beck is an anticancer agent. Thus, the steps are the same. Beck discloses methods that do not have a coating step. However, the claimed methods do not exclude a coating step, as the method claims recite, "comprising" which is open-ended to additional steps. The "consisting essentially of" later in the claim would, at most, only require that one start with nanoparticles having mainly only the components listed thereafter in the method. However, the method, as claimed, would not exclude a coating step later on, as the claim states that the method recites "comprising" terminology as to the steps involved.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 102, 105, 108, 112, 114, 117, 118, 120, 122, 133, 135 and 136 are rejected under 35

U.S.C. 103(a) as being unpatentable over either one of Reszka (The Jour. of Pharmaco. and Exp.

Therap., 1/1997, AW-PTO-1449) or Beck (Jour. of Microencapsulation, 1993, PTO-892) in view of Kreuter (WO 95/22963), for the reasons set forth in the office action mailed 12/8/2003.

Applicant's arguments filed 6/8/2004 have been fully considered but they are not persuasive.

Applicant reiterates that argument provided above for Reszka and Beck and asserts that Kreuter requires the use of a coating.

This is not found persuasive as Kreuter is only relied upon for teaching the use of various drugs as equivalents to provide the desired pharmaceutical action in nanoparticle formulations.

Applicant asserts the Reszka, Beck and Kreuter all teach that a coating is critical to decrease uptake by the RES.

This is not found persuasive because Reszka and Beck disclose methods that do not have a coating step, while Kreuter is only relied upon for teaching the equivalence of various drugs in drug nanoparticles. Further, such an argument cannot be used to differentiate the pending claims, as the method claims presented, of preparing a nanoparticle formulation, recite "comprising" which is open-ended as far as additional steps are concerned and would not exclude a step of coating the nanoparticles as asserted by applicant.

Allowable Subject Matter

Claim 110 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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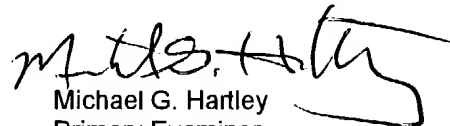
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-Tu and Th-F, 7:30-4, Telework on Wed..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael G. Hartley
Primary Examiner
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7/19/2004